

Amendments to the Specification:

The Title on the first and last pages has been amended as follows:

5 METHOD OF IMPLANTING A SELF-MOLDING ANNULOPLASTY RING AND
METHOD OF USE

The following “Related Applications” has been added to page 1:

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The present application is a continuation of Serial No. 09/938,902, filed August 24, 2001, entitled SELF-MOLDING ANNULOPLASTY RING, which application is expressly incorporated herein by reference.

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The paragraph beginning on page 4, line 9 of the parent application has been amended as follows:

20 [0020] Figure 3A shows a top sectional view of the annuloplasty ring of the present invention positioned within the valve annulus of the mitral valve;

The paragraph beginning on page 5, line 18 of the parent application has been divided into three paragraphs (0030, 0031, 0032) and has been amended as follows:

25 [0030] Various views of the present invention are illustrated in Figures 2A-2E. As shown in Figure 2A, the self-molding annulus ring 20 comprises a first planar surface 22 and an opposing second planar surface 24. Figure 2B shows the annulus ring 20 having a rectilinear

segment 26 and an arcuate segment 28 connected by two curved ends 30 and 32, respectively. As illustrated, the preferred annuloplasty ring 20 is generally “D” shaped to conform to the shape of a typical mitral valve annulus. Alternatively, the ring 20 may be manufactured in any shape suitable for implantation about an annulus. For example, the present invention may be
5 manufactured in a generally round or oval shape thereby permitting use of the present invention to remodel an otherwise incompetent tricuspid valve. Figure 2C shows a cross-sectional view of the annuloplasty ring 20 having an elastic sizing member 36 positioned within an attachment sheath 38. While the cross-sectional view illustrated in Figure 2C is substantially rectangular, it is to be appreciated that the cross-section can alternatively be of another dimension such as
10 triangular, circular or any dimension that cooperates with the native annulus.

[0031] The elastic sizing member 36 preferably comprises a biologically-compatible materials such as, without limitation, elastomer, silicon, or any other material having sufficient resiliency to permit pre-stretching of the annuloplasty ring 20 prior to and during implantation, while having sufficient contractive force to decrease the size of the valve annulus to a desired
15 diameter. The attachment sheath 38 provides a suitable material for suturing or otherwise attaching the annulus ring 20 to the annulus tissue and promoting tissue growth therein. The attachment sheath 38 preferably comprises a biologically-compatible material such as, without limitation, Dacron (polyethylene terephthalate), polyester knit, PTFE knit, and ePTFE knit. The attachment sheath may also be treated with a biologically-compatible tissue growth factor or
20 other medicament to aid in treating the attachment area. Those skilled in the art will appreciate that the present invention reduces or eliminates the occurrence of systolic anterior motion (SAM), wherein the anterior leaflet of the mitral valve bulges into the left ventricular outflow track (LVOT) thereby obstructing blood flow into the aorta.

[0032] An alternate embodiment of the present invention is shown in Figure 2D having
25 support members 40 positioned between the sizing member 36 and the attachment sheath 38. The support members 40 are preferably fabricated from a biologically-compatible materials having a comparable modulus of resiliency such as, without limitation, elastomer, rubber, silicon,

or another material having sufficient resiliency to permit pre-stretching prior to implantation while sufficient providing support to the valve annulus. The support member 40 provides additional support of the valve and valve annulus Figure 2E shows a perspective view of the annuloplasty ring of the present invention.

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The paragraph beginning on page 6, line 25 of the parent application has been divided into two paragraphs (0033, & 0034) and has been amended as follows:

10 [0033] The annuloplasty ring of the present invention may be attached to the annulus or surrounding tissue using a plurality of devices. Referring to ~~Figures~~ Figure 3A, the annulus ring 20 may be attached to the valve annulus, either 14 or 18, with sutures 42. Figure 3B shows an alternate embodiment of the present invention utilizing attachment devices positioned on the annuloplasty ring. Like the previous embodiments, the present embodiment of the ring 44 comprises a rectilinear segment 46 attached to an arcuate portion 48 with two curved ends 50 and 15 52 positioned therebetween. A number of attachment devices 54 are positioned around the ring 44 to facilitate attachment of the ring 44 to the annulus tissue. Figure 3C shows the internal materials of the present invention having a sizing member 56 and a tissue-engaging sheath 58 disposed thereon.

20 [0034] Like the previous embodiments, the sizing member 56 is preferably manufactured from a biologically-compatible material such as, without limitation, elastomer, silicon, or any other material having sufficient resiliency to permit pre-stretching of the annuloplasty ring 44 prior to and during implantation, while having sufficient contractive force to decrease the size of the valve annulus to a desired diameter. Similarly, the tissue-engaging sheath 58 is preferably manufactured from a biologically-compatible material having comparable resiliency, such as, 25 without limitation, Dacron (polyethylene terephthalate), polyester knit, PTFE knit, and ePTFE knit, and may further incorporate tissue growth-enhancing materials. The attachment device 54 may comprise various tissue-engaging devices, including, for example, needles, barbs, or hooks.

Those skilled in the art will appreciate the attachment devices 54 is preferably manufactured from a biologically-compatible material such as, without limitation, stainless steel, titanium, or Nickel-Titanium alloy (Nitinol). Figure 3D shows a perspective view of the annuloplasty ring of the present embodiment having a plurality of attachment devices 54 positioned about the device
5 body 44.

The paragraph beginning on page 7, line 19 of the parent application has been divided into two paragraphs (0035, & 0036) and has been amended as follows:

10 [0035] Figures 4A-4C show an alternative embodiment of the present invention which includes size constraining support members. Figure 4A shows the annuloplasty ring 60 of the present embodiment in a contracted state, wherein the ring 60 comprises a rectilinear segment 62, an arcuate segment 64, and two curved ends 66 and 68 positioned therebetween. The ring 60 is comprised of a series of support members 70 positioned about the device. The support members
15 70 are positioned immediately adjacent to each other in the contracted state, though it is to be understood that the resilient inner sizing member is biased toward a fully relaxed diameter that is smaller than the diameter in the contracted state. In other words, the plurality of support members 70 constrain contraction of the inner sizing member 72 to a contracted diameter that is larger than the fully relaxed diameter. Figure 4B shows the ring 60 stretched prior to
20 implantation, having the resilient inner sizing member 72 positioned within the support members 70. As shown in Figure 4C, each support member 70 has a receiving lumen 74 formed therein which is capable of receiving the inner sizing member 72. The attachment sheath 76 may be positioned on the exterior of the support members 70. Prior to implantation, the ring 60 is pre-stretched to a fully expanded diameter roughly equivalent to the diameter of the dilated valve
25 annulus and the attachment sheath is attached to the tissue using, for example, sutures, staples, or barbs. Once the ring 60 is suitably positioned with the valve annulus and attached thereto, the insertion device (not shown) is removed and the ring 60 contracts causing each size support

member 70 to engage the adjacent support members 70, thereby limiting the degree of contraction that the ring 60 may achieve. Again, the plurality of support members 70 constrain contraction of the inner sizing member 72 to a contracted diameter that is smaller than the fully expanded diameter but larger than the fully relaxed diameter.

5 [0036] The support members 70 are preferably manufactured from a biologically-compatible material such as, without limitation, stainless steel, titanium, or plastic. Like the previous embodiment, the inner sizing member 72 is preferably manufactured from a biologically compatible material such as, without limitation, elastomer, silicon, or any other material having sufficient resiliency to permit pre-stretching of the annuloplasty ring 60 prior to and during
10 implantation, while having sufficient contractive force to decrease the size of the valve annulus to a desired diameter. Similarly, the attachment sheath 76 is preferably manufactured from a resilient biologically-compatible material such as, without limitation, Dacron (polyethylene terephthalate), polyester knit, PTFE knit, and ePTFE knit, or may incorporate tissue growth-enhancing materials.

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